Docket No.: 22719-23RCE
(PATENT)

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of: David D. Konieczynski et al.	
Application No.: 10/092,954	Confirmation No.: 7357
Filed: March 6, 2002	Art Unit: 3767
For: CONVECTION-ENHANCED DRUG DELIVERY DEVICE AND METHOD OF USE	Examiner: S. Kennedy

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By: William C. Geary III

SUPPLEMENTAL APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

IN RESPONSE TO NOTIFICATION OF NON-COMPLIANT APPEAL BRIEF

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REAL PARTY IN INTEREST

The real party in interest for this appeal is Codman & Shurtleff, Inc., a Johnson & Johnson Company. Codman & Shurtleff, Inc., of Raynham, Massachusetts, derives its rights in this application by virtue of an assignment of the application by the inventors to Codman & Shurtleff, Inc.

RELATED APPEALS, INTERFERENCES, AND JUDICIAL PROCEEDINGS

None.

STATUS OF CLAIMS

Claims 1, 3, 7, 8, 10, 11, 14-17, 19, 20, 25, and 28-40 are currently pending in the present application, Serial No. 10/092,954. According to the Office Action mailed on June 1, 2005, claims 1, 3, 10, 11, 15, 17, and 28-39 stand rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,569,186 of Lord et al, claims 1, 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25, and 28-40 stand rejected pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2004/0034332 of Uhland, and claims 7, 8, 14, 19, 20, 22 and 25 stand rejected pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,569,186 of Lord et al. in view of U.S. Patent No. 5,797,898 of Santini et al.

Accordingly, claims 1, 3, 7, 8, 10, 11, 14-17, 19, 20, 25, and 28-40 are subject to appeal.

STATUS OF AMENDMENTS

Applicant did not submit any claim amendments subsequent to the Final Rejection.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides an implantable drug delivery system 10, 100 for delivery of a drug material into a target tissue. Independent claim 1 recites an implantable drug delivery system 10, 100 having an infusion pump 20, 120 including a fluid outlet and a fluid delivery line 40, 140 effective for extending from the fluid outlet to a discharge portion positionable at a target tissue site (See, e.g., page 7, lines 12-16 of the specification). A controlled release drug assembly 25, 130a is downstream from the infusion pump 20, 120 and is configured for

controllably releasing drug material and communicating with the fluid delivery line 40, 140 such that the drug material is released into the fluid delivery line 40, 140 (See, e.g., page 8, lines 17-18 and 30-34). The pump assembly is effective to deliver a carrier fluid to the fluid outlet such that the drug material released into the delivery line discharges at the discharge portion to treat the target tissue site (See, e.g., page 7, lines 16-24).

Independent claim 29 recites a method for infusing a drug into a target tissue site of a subject. The method includes providing an infusion pump assembly. The pump assembly includes a carrier fluid source 24, and is effective to convey a fluid within the pump through a fluid delivery line 40 to a discharge portion positionable at a target tissue site (See, e.g., page 7, lines 12-16). The method further includes providing an implantable drug release assembly 30 in communication with the fluid delivery line 40 and downstream from the infusion pump 20. The release assembly 30 has at least one drug reservoir configured for controlled release of a drug into the fluid delivery line 40 (See, e.g., page 8, lines 20-22). A carrier fluid is enabled to be delivered under pressure from the infusion pump assembly 20 at a desired flow rate through the fluid delivery line 40 to transport drug released by the drug release assembly 30 to the target tissue site (See, e.g., page 8, lines 2-4).

Independent claim 40 recites a method of delivering a drug or bioactive material to target tissue such as tissue of the central nervous system (CNS). The method includes providing an infusion pump 20 having an output connectable with a delivery line 40 implantable at a target tissue site, and providing an implantable controlled release drug device 30 attachable downstream from the infusion pump 20 and in communication with the delivery line 40 (See, e.g., page 7, lines 12-16). The controlled release drug device 30 is effective to release drug into carrier fluid pumped by the infusion pump 20. The carrier fluid is thereby delivered to the target tissue site with the drug (See, e.g., page 7, lines 18-20). The pump is controllable to maintain an elevated delivery pressure such that the drug achieves a convectively enhanced profile in tissue at the target tissue site (See, e.g., page 9, lines 15-19).

As stated in the "Background of the Invention" of the present application, several different tools and methods are used to delivery medications to treat conditions in the body. In some instances, such as in the case of the central nervous system (CNS), a direct administration of drug material is preferable. The current implantable systems for delivering drugs employ a

pump and a catheter to deliver the drug material. Even with the addition of a microchip delivery device to hold drug doses, the drugs are delivered by diffusion, thus causing a greatly diminished drug concentration to the target area. To overcome these problems, Applicants have developed a system which provides efficient drug delivery of one or more drug materials to a target tissue while preserving the range and/or concentration of the drug material for delivery.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the Examiner improperly rejected claims 1, 3, 10, 11, 15, 17, and 28-39 pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,569,186 of Lord et al.

2. Whether the Examiner improperly rejected claims 1, 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25, and 28-40 pursuant to 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2004/0034332 of Uhland.

3. Whether the Examiner improperly rejected claims 7, 8, 14, 19, 20, 22 and 25 pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,569,186 of Lord et al. in view of U.S. Patent No. 5,797,898 of Santini et al.

ARGUMENT

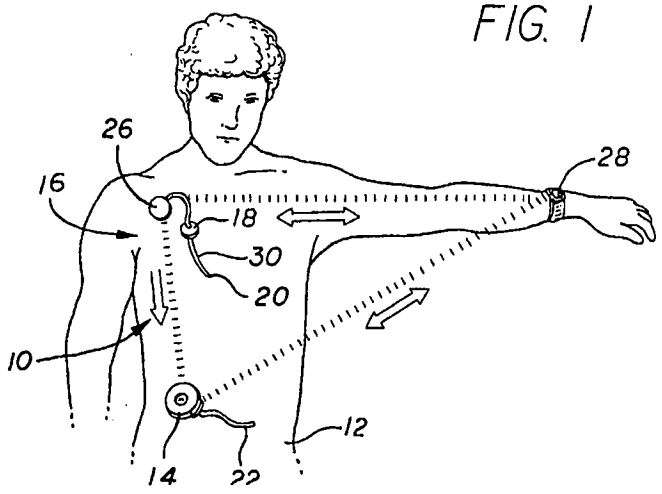
A. Rejection Pursuant to 35 U.S.C. 102(b) Over U.S. Patent No. 5,569,186 of Lord et al.

1. The Examiner's Rejection Over Lord and the Scope and Content of the Prior Art

Claims 1, 3, 10-11, 15, 17, and 28-39 are finally rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,569,186 of Lord et al.

Lord is directed to an infusion pump containing insulin for release into a patient through communication with a sensor using radio telemetry (or a cable as shown in FIG. 4) to control the insulin

FIG. 1



release. FIG. 1 of Lord is reproduced herein. As shown, Lord teaches an infusion pump (14) containing insulin and control circuitry. The control circuitry housed in the infusion pump (14) controls the release of insulin from a catheter (22) based on patient need or in response to blood glucose measurements taken by a sensor unit (16). The sensor unit (16) is located remote of the pump and includes a telemetry unit (26) which can transmit the blood glucose measurements to the infusion pump (14) to control the insulin release.

2. Lord Does Not Disclose Each and Every Element of Appellant's Claimed Invention

The Examiner has failed to establish that Lord discloses the recitations of Appellant's claims.

Appellant's claim 1 recites an implantable drug delivery system. The system comprises an infusion pump including a fluid outlet and a fluid delivery line effective for extending from the fluid outlet to a discharge portion positionable at a target tissue site. Further, a controlled release drug assembly is positioned downstream from the infusion pump. The drug assembly is configured for controllably releasing drug material and communicating with the fluid delivery line so the drug material is released into the fluid delivery line. The pump assembly is effective to deliver a carrier fluid to the fluid outlet so the drug material released into the delivery line discharges at the discharge portion to treat the target tissue site.

Lord does not teach or suggest a discharge portion positionable to treat a target tissue site. As shown in FIG. 1, catheter 22, which delivers insulin to a patient, is not positioned at a target tissue as recited in the independent claims of the invention. Instead, Lord teaches that medication is delivered systemically to a patient through catheter 22 which discharges the insulin near the site of the infusion pump. There is no suggestion in Lord to position catheter 22 at a target tissue site. Further, insulin delivery is the only use suggested for the infusion pump in Lord. Insulin, by its very nature, does not have a target tissue but rather is released into the patient and is diffused throughout the body to affect blood glucose levels. Thus, there is no reason why Lord would even require drug delivery to target tissue.

Further, Lord does not teach a controlled release drug assembly positioned *downstream* from an infusion pump. Lord does not teach a separate infusion pump and controlled release

drug assembly as recited in claim 1. Rather, as shown, for example, in FIG. 1 of Lord, a pump containing insulin for release into a patient communicates with a sensor through radio telemetry (or a cable as shown in Lord's FIG. 4) to control the insulin release. The system described in Lord merely houses insulin within an infusion pump and delivers an appropriate dose to the patient without the need for a carrier fluid. Thus, there is no suggestion in Lord of an infusion pump with a drug assembly positioned downstream therefrom.

The Examiner seems to be confused by the use of the word "downstream" in claim 1. In the Advisory Action dated October 5, 2005, the Examiner states "the word downstream in the dictionary means "away from the source", and Lord teaches a drug assembly away from the pump." Lord does not have a separate drug assembly located away from the pump. Rather, and as noted above, the only drug disclosed by Lord *is present in the pump*, not away from it. Perhaps the Examiner is confused by Lord's sensor 16, which is remote from the pump. the presence of the sensor has no impact on Appellant's claim and it does not change the fact that Lord's disclosure completely fails to teach a drug assembly downstream from an infusion pump. This claimed structural difference should be sufficient to render Lord inapplicable as an anticipatory reference.

Accordingly, claim 1, and claims 3, 10-11, 15, 17, and 28 which depend therefrom distinguish over Lord and represent allowable subject matter.

Independent claim 29 recites a method for infusing a drug into a target tissue site of a subject. The method comprises the steps of providing an infusion pump assembly, where the pump assembly includes a carrier fluid source and the infusion pump assembly is effective to convey a fluid within the pump through a fluid delivery line to a discharge portion positionable at a target tissue site. Further, the method includes providing an implantable drug release assembly in communication with the fluid delivery line and downstream from the infusion pump. The release assembly has at least one drug reservoir configured for controlled release of a drug into the fluid delivery line. The method further includes enabling a carrier fluid to be delivered under pressure from the infusion pump assembly at a desired flow rate through the fluid delivery line to transport drug released by the drug release assembly to the target tissue site.

Lord is not relevant to claim 29 because it does not teach providing an implantable drug release assembly in communication with a fluid delivery line and downstream from an infusion pump. As discussed above with respect to claim 1, Lord simply does not disclose anything that resembles a drug release assembly that is separate from the pump and certainly not one that is downstream from the infusion pump. Lord only has one drug-containing component - the infusion pump 14, and Lord's system does not have any further components in fluid communication with the infusion pump.

Further, Lord does not teach an infusion pump assembly which includes a carrier fluid source, and is effective to convey a fluid within the pump through a fluid delivery line to a discharge portion positionable at a target tissue site. As noted above while addressing the rejection of claim 1, the device of Lord does not utilize a carrier fluid. Rather, insulin (the only drug disclosed by Lord) is delivered to a patient through catheter 22, which discharges the insulin near the site of the infusion pump. There is no suggestion in Lord to position catheter 22 at a target tissue site in the teachings of Lord. Further, as stated above, insulin, by its very nature, does not have a target tissue but rather is released into the patient and is diffused throughout the body to affect blood glucose levels. Thus, Lord would not require target tissue delivery.

Accordingly, claim 29 and claims 30-39 which depend therefrom, distinguish over Lord and represent allowable subject matter.

B. Rejection Pursuant to 35 U.S.C. 102(e) Over U.S. Publication No. 2004/0034332 of Uhland.

1. The Examiner's Rejection Over Uhland and the Scope and Content of the Prior Art

Claims 1, 3, 7-8, 10-11, 14-17, 19-20, 22, 25 and 28-40 are finally rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Publication No. 2004/0034332 of Uhland.

Uhland is directed to a microchip device containing reservoirs of molecules for controlled release. The device can be used in a variety of implementations, including its implantation into a patient as part of a micropumping system such as the one disclosed in U.S. Patent No. 4,596,575 of Rosenberg (reference to which is made in paragraphs 108 and 109 of

Uhland). Uhland does not disclose a substantial teaching of how a micropumping system would function, and merely states:

> In another embodiment, a microchip device is incorporated into an implantable micropumping system, for example for the delivery of drugs over extended periods of time, such as is needed the delivery of insulin to diabetics and treating certain kind of severe chronic pain. Micropump apparatus suitable for use in these devices are known in the art (see, e.g., U.S. Pat. No. 4,596,575 to Rosenberg). The micropump pumps carrier fluid across one or more surfaces of the microchip device. A variety of carrier fluids can serve as the pumped fluid, including, but not limited to, filtered extra-cellular fluid, saline solution, or water.
>
> In a preferred embodiment, release of doses is actively controlled, such as by disintegration of reservoir caps via electrochemical dissolution, as described in U.S. Pat. No. 5,797,898 and No. 6,123,861 to Santini. The release system preferably is in the form of a solid that is soluble in the carrier fluid. As the fluid passes over or around the activated and opened reservoir, the solid drug dissolves in the carrier fluid, forming a solution that is pumped into the extra-cellular environment.

Uhland, paragraphs 108 and 109. Rosenberg's disclosure does not supplement Uhland's teaching to any significant extent as it only teaches a liquid delivery system used as an implantable drug infusion device. Referring to FIG. 1 of Rosenberg, a liquid, such as insulin, is housed with unit (4) and pumped into the body through feed tube 7.

2. Uhland Does Not Disclose Each and Every Element of Appellant's Claimed Invention

The Examiner has failed to establish that Uhland discloses the limitations of Appellant's claims.

Uhland does not teach or suggest that the fluid delivery line extends from the fluid outlet to a discharge portion positionable at a target tissue site as recited in the independent claims 1, 29, and 40. Even if the teachings of Rosenberg can be considered to be incorporated into Uhland's disclosure, Uhland still does not disclose how a pump employing the microchip device would function, specifically with regard to the location of fluid delivery. Thus, there is no mention in Uhland of directing fluid to a target tissue site. Even to the extent that it is possible to incorporate Rosenberg by reference, Rosenberg does not teach or suggest positioning the feed

tube at a target tissue site. Instead of a discharge portion positioned at a target tissue, the fluid from the micropump is released at a position proximate to the micropump itself and diffused through the body. Uhland thus fails to disclose or suggest release at the site of a target tissue.

Accordingly, independent claims 1, 29 and 40, and claims 3, 7, 8, 10, 11, 14-17, 19, 20, 22, 25, and 28 which depend on claim 1 and claims 30-39 which depend on claim 29, distinguish over Uhland.

C. Rejection Pursuant to 35 U.S.C. 103(a) Over The Combination of U.S. Patent No. 5,569,186 of Lord et al. and U.S. Patent No. 5,797,898 of Santini et al.

Claims 7-8, 14, 19, 20, 22, and 25 are finally rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,569,186 of Lord et al. in view of U.S. Patent No. 5,797,898 of Santini.

The Examiner relies on Lord as the primary reference arguing that "Lord teaches the invention except for a microchip. Santini teaches a use of microchip in drug delivery" (page 4 of the Office Action dated June 1, 2005). The Examiner states that it would have been obvious to add the microchip because Santini teaches a microchip that allows for a variety of delivery rates and storage for a variety of types of drugs.

1. Lord Fails to Teach the Present Invention

As discussed above, Lord fails to teach or suggest all the elements of the claimed invention. Specifically, Lord does not teach a fluid delivery line to a discharge portion positionable at a target tissue site or an implantable drug release assembly in communication with the fluid delivery line and downstream from the infusion pump.

2. Santini Does Not Remedy the Deficiencies of Lord

Santini is directed to microchip for the delivery of molecules at controlled rates. The device contains a plurality of reservoirs containing the molecules, such as a drug material, to be delivered.

There is no mention in Santini of an infusion pump such as the one described in the claims of the present application. For example, Santini does not teach a fluid delivery line to a

discharge portion positionable at a target tissue site or an implantable drug release assembly in communication with the fluid delivery line and downstream from the infusion pump. Accordingly, Santini does not remedy the deficiencies of Lord.

Accordingly, none of the references, either alone or combined, include all of the elements of the claims. These references cannot render the claimed invention obvious. Claims 7-8, 14, 19, 210, 22, and 25 therefore represent allowable subject matter.

CONCLUSION

For the reasons noted above, Appellant submits that the pending claims define patentable subject matter. Accordingly, Appellant requests that the Examiner's rejection of these claims be reversed and that the pending application be passed to issue.

Dated: 11-30-06

Respectfully submitted,

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CLAIMS APPENDIX: CLAIMS ON APPEAL

1. (Previously Presented) An implantable drug delivery system, comprising:

an infusion pump including a fluid outlet;

a fluid delivery line effective for extending from the fluid outlet to a discharge portion positionable at a target tissue site; and

a controlled release drug assembly downstream from the infusion pump, said drug assembly being configured for controllably releasing drug material, and communicating with said fluid delivery line such that the drug material is released into said fluid delivery line,

wherein the pump assembly is effective to deliver a carrier fluid to the fluid outlet such that the drug material released into the delivery line discharges at the discharge portion to treat the target tissue site.

2. Withdrawn.

3. (Original) The system of claim 1, wherein the pump includes a chamber for holding a predetermined quantity of carrier fluid.

4.-6. Withdrawn.

7. (Previously presented) The system of claim 1, wherein the controlled release drug assembly is a microchip having at least one drug reservoir, and wherein the microchip is in fluid communication with the fluid delivery line intermediate to the pump and the target tissue site.

8. (Previously presented) The system of claim 7, wherein the microchip is located in the fluid delivery line.

9. Withdrawn.

10. (Original) The system of claim 1, wherein the carrier fluid is a fluid selected from the group consisting of a physiological buffer, a pharmaceutical excipient or adjuvant, an endogenous fluid, and combinations thereof.

11. (Original) The system of claim 10, wherein the carrier fluid is an endogenous fluid selected from the group consisting of cerebral spinal fluid, blood, lymphatic fluid, components thereof, and combinations thereof.

12.-13. Withdrawn.

14. (Original) The system of claim 1, wherein the infusion pump includes a microcontrol unit that controls flow rate of the pump.

15. (Original) The system of claim 1, wherein the infusion pump is effective to pump at a rate to drive convection-enhanced transport into the target tissue site, thereby enhancing effective delivery profile at the target site.

16. (Original) The system of claim 1, wherein the flow rate ranges from about 0.5 to about 20 microliters per minute.

17. (Original) The system of claim 1, wherein the pump assembly includes a pump assembly selected from among the group consisting of a pressurized reservoir, a peristaltic pump, a diaphragm pump, and a piston pump.

18. Withdrawn.

19. (Original) The system of claim 1, wherein the drug release assembly includes a microchip powered by a power source.

20. (Original) The system of claim 14, wherein the microchip is in communication with the microcontrol unit.

21. Withdrawn.

22. (Original) The system of claim 1, wherein the drug release assembly includes a microchip containing one or more drugs therein.

23.-24. Withdrawn.

25. (Original) The system of claim 1, wherein the drug release assembly is a microchip having a plurality of reservoirs containing plural different drugs, drug concentrations, or a combination thereof.

26.-27. Withdrawn.

28. (Original) The system of claim 1 further comprising an array of biosensors disposed in tissue, and wherein at least one of the infusion pump and the controlled drug release assembly responds to biosensor signals from the array.

29. (Previously Presented) A method for infusing a drug into a target tissue site of a subject, the method comprising the steps of:

providing an infusion pump assembly, wherein the pump assembly includes a carrier fluid source, wherein the infusion pump assembly is effective to convey a fluid within the pump through a fluid delivery line to a discharge portion positionable at a target tissue site;

providing an implantable drug release assembly in communication with the fluid delivery line and downstream from the infusion pump, said release assembly having at least one drug reservoir configured for controlled release of a drug into the fluid delivery line; and

enabling a carrier fluid to be delivered under pressure from the infusion pump assembly at a desired flow rate through the fluid delivery line to transport drug released by the drug release assembly to the target tissue site.

30. (Original) The method of claim 29, wherein the pump assembly is effective to deliver carrier fluid at a rate effective to induce convective bulk transport of the drug into tissue at the target site.

31. (Original) The method of claim 30, wherein the target site is brain tissue and the pump assembly is effective to deliver carrier fluid at a rate in the range of about 0.5 to about 20 microliters/minute to induce convective bulk transport of the drug into brain tissue.

32. (Previously presented) The method of claim 29, wherein the fluid delivery line terminates in a distal end, wherein the distal end is implantable within the target site.

33. (Original) The method of claim 29, wherein the one or more drugs are released in a delivery regimen selected from among a pulsatile, an intermittent and a continuous delivery regimen.

34. (Previously presented) The method of claim 29, further including the step of providing a biosensor in at least one of the fluid delivery line, the tissue site and the controlled release assembly, and controlling at least one of the infusion pump assembly and the drug release assembly in response to biosensor signals.

35. (Original) The method of claim 29, further including the step of detecting a material or condition with a biosensor array, and controlling at least one of the infusion pump assembly and the drug release assembly in response thereto.

36. (Original) The method of claim 29, wherein the carrier fluid is selected from the group consisting of a physiological buffer, a pharmaceutical excipient or adjuvant, an endogenous fluid, and combinations thereof.

37. (Original) The method of claim 29, wherein the carrier is an endogenous fluid selected from the group consisting of cerebral spinal fluid, blood, lymphatic fluid, components thereof, and combinations thereof.

38. (Original) The method of claim 29, wherein the infusion pump assembly is operable to continuously maintain enhanced fluid pressure over a predetermined period of time.

39. (Original) The method of claim 29, wherein a microcontrol unit disposed within the infusion pump controls fluid delivery pressure profile over a predetermined period of time.

40. (Previously Presented) A method of delivering a drug or bioactive material to target tissue such as tissue of the central nervous system (CNS), such method comprising the steps of

providing an infusion pump having an output connectable with a delivery line implantable at a target tissue site; and

providing an implantable controlled release drug device attachable downstream from the infusion pump and in communication with the delivery line, such that the controlled release drug device is effective to release drug into carrier fluid pumped by the infusion pump;

thereby delivering the carrier fluid to the target tissue site with said drug, the pump being controllable to maintain an elevated delivery pressure such that the drug achieves a convectively enhanced profile in tissue at the target tissue site.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None

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